

System of terminology, said Pap smear including atypical and normal endocervical cells, said method comprising:

(A) subjecting said AGUS-diagnosed Pap smear cells to a procedure whereby MN/CA9 antigen is detected ;

(B) observing the distribution of MN/CA9 antigen on atypical or normal cells of said AGUS cytologically diagnosed Pap smear cells;

(C) diagnosing the presence of significant lesions based on the observation of said MN/CA9 antigen on said atypical cells, wherein the significant lesions include adenocarcinoma, invasive carcinoma (CA), or high grade squamous intraepithelial lesions (HSIL); and

A³ (D) diagnosing the presence of low grade lesions based on the observation that said MN/CA9 antigen is absent from said atypical cells but is present on said normal endocervical cells, wherein the low grade lesions include low grade squamous intraepithelial lesions (LSIL) or atypia.

2. (Amended) The method of claim 1, further comprising:

(E) diagnosing a benign condition based on the observation that said MN/CA9 antigen is absent from said atypical cells and normal endocervical cells.

3. (Amended) A method for determining the presence of adenocarcinoma from Pap smear cells that have been cytologically diagnosed as atypical glandular cells of undetermined significance (AGUS) under the Bethesda System of terminology, said Pap smear including atypical and normal endocervical cells, said method comprising:

(A) subjecting said AGUS-diagnosed Pap smear cells to a procedure whereby MN/CA9 antigen is detected;

(B) observing the distribution of MN/CA9 antigen on atypical or normal cells of said AGUS cytologically diagnosed Pap smear cells; and

(C) diagnosing the presence of adenocarcinoma based on the observation of said MN/CA9 antigen on said atypical cells in a honeycomb configuration.

4. (Amended) The method of claim 3, wherein said adenocarcinoma is adenocarcinoma in situ (AIS) or invasive adenocarcinoma.

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5. (Amended) A method for determining the presence of high grade squamous intraepithelial lesions from Pap smear cells that have been cytologically diagnosed as atypical glandular cells of undetermined significance (AGUS) under the Bethesda System of terminology, said Pap smear including atypical and normal endocervical cells, said method comprising:

(A) subjecting said AGUS-diagnosed Pap smear cells to a procedure whereby MN/CA9 antigen is detected;

(B) observing the distribution of MN/CA9 antigen on atypical or normal cells of said AGUS cytologically diagnosed Pap smear cells; and:

(C) diagnosing the presence of high grade squamous intraepithelial lesions (HSIL) based on the observation of said MN/CA9 antigen on said atypical cells in a tight cluster.

6. (Amended) A method for determining the presence of significant cancerous or pre-cancerous cervical lesions from Pap smear cells that have been cytologically diagnosed as atypical glandular cells of undetermined significance (AGUS) under the Bethesda System of terminology, said Pap smear including atypical and normal endocervical cells, said method comprising:

(A) subjecting said AGUS-diagnosed Pap smear cells to a procedure whereby MN/CA9 antigen is detected;

(B) observing the distribution of MN/CA9 antigen on atypical or normal cells of said AGUS cytologically diagnosed Pap smear cells;

(C) diagnosing the presence of significant lesions based on the observation of said MN/CA9 antigen on said atypical cells, wherein the significant lesions include adenocarcinoma, invasive carcinoma, or high grade intraepithelial lesions;

(D) diagnosing the presence of adenocarcinoma based on the observation of said MN/CA9 antigen on said atypical cells in a honeycomb configuration; and

(E) diagnosing the presence of high grade squamous intraepithelial lesions (HSIL) based on the observation of said MN/CA9 antigen on said atypical cells in a tight cluster.

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7. (Amended) A method for determining the presence of low grade cervical lesions from Pap smear cells that have been cytologically diagnosed as atypical glandular cells of undetermined significance (AGUS) under the Bethesda System of terminology, said Pap smear including atypical and normal endocervical cells, said method comprising:

(A) subjecting said AGUS-diagnosed Pap smear cells to a procedure whereby MN/CA9 antigen is detected;

(B) observing the distribution of MN/CA9 antigen on atypical and normal cells of said AGUS cytologically diagnosed Pap smear cells; and

(C) diagnosing the presence of low grade squamous intraepithelial lesions (LSIL) or atypia based on the observation that said MN/CA9 antigen is absent from said atypical cells but is present on said normal endocervical cells.

8. (Amended) A method for determining the presence or absence of cancerous or pre-cancerous cervical lesions from Pap smear cells that have been cytologically diagnosed as atypical glandular cells of undetermined significance (AGUS)

under the Bethesda System of terminology, said Pap smear including atypical and normal endocervical cells, said method comprising:

(A) subjecting said AGUS-diagnosed Pap smear cells to a procedure whereby a characterizing fraction of an MN/CA9 protein is detected, said characterizing fraction comprising at least one antigenic determinant or immunoreactive epitope of the MN/CA9 protein, which binds detectably to an anti-MN/CA9 antibody; and

(B) observing the distribution of MN/CA9 antigen on atypical or normal cells of said AGUS cytologically diagnosed Pap smear;

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(C) diagnosing the presence of adenocarcinoma, based on the observation of said MN/CA9 antigen on said atypical cells in a honeycomb configuration;

(D) diagnosing the presence of high grade squamous intraepithelial lesions (HSIL) based on the observation of said MN/CA9 antigen on said atypical cells in a tight cluster;

(E) diagnosing the presence of low grade squamous intraepithelial lesions (LSIL) and/or atypia based on the observation that said MN/CA9 antigen is absent from said atypical cells but is present on said normal endocervical cells; and

(F) diagnosing a benign condition based on the observation that said MN/CA9 antigen is absent from said atypical cells and normal endocervical cells.

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44. (Amended) The method of claim 8, wherein said MN/CA9 antigen is detected by immunohistochemistry.